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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,916	04/07/2006	Niels Joergen Madsen	P71166US0	8853

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

GHALL, ISIS A D

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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06/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,916

Applicant(s)

MADSEN ET AL.

Examiner

Isis A. Ghali

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 14-20, 22-25 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-13, 21, 26 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 05/10/2010.

Claims 1-36 previously presented. Claims 37-42 are currently added.

Claims 1-42 are pending.

Claims 1, 6-13, 21, 26 and 37-42 are included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Election/Restrictions

2. Applicants argue that the election was made with traverse because applicants' aforesaid in the response to election/restriction requirement: "Traverse is maintained because the requirement (Office Action, page 10) incorrectly states: "The examiner has

required restriction between product and process claims." On the contrary, the examiner has not required "restriction between product and process claims"--- or any other "restriction," for that matter--and, so, applicants have made no election (hereby) between product and process claims. Consequently, neither product nor process claims (as a group) can be withdrawn from consideration pursuant to the instant election of species.

In response to this argument, as set forth in the previous office action, it is repeated that that "the examiner inadvertently inserted the paragraph 17 in page 10 that concerns restriction between product and process. This paragraph is hereby withdrawn." Therefore, not restriction has even made between product and process, and therefore, response to this kind of restriction is moot and not further applicable.

Applicants argue that: How the aforesaid statement "did not distinctly and specifically point out the supposed errors in the restriction requirement" defies reason and logic, with all due respect. Accordingly, applicants' election was made with traverse in the response filed October 15, 2009 in the PTO, allegations to the contrary in the instant Office Action notwithstanding, and the traverse is maintained.

In response to this argument, it is clarified that no election was made between product and process, however species election was made. Although applicants did elect single species from each category, however did not traverse the species election and did not state the species are not distinct and did not show that the species are obvious variant. Therefore, election between different species was not traversed.

3. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 2-5, 14-20, 22-25, 27-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/15/2009.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 6-13, 21, 26 and 37-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 as amended recites "one or more hydrophilic polymer end blocks". However, recourse to the specification, applicants disclosed the hydrophilic block is end block only in AB polymer.

In case of triblock, the hydrophilic block forms the mid-block. Paragraphs [0048], [0049] and [0084] stated:

[0084] "Preferred amphiphilic block copolymers to be used in accordance with the present invention are such wherein the A domain is a thermoplastic polymer end block of a mono vinyl aromatic homo polymer, preferably one having at least two different molecular weight end blocks in the copolymer (e.g., one A block of about 1000 to about 50,000 number average molecular weight and a B block of about 1000 to about 500,000 number average molecular weight), where the B domain is a hydrophilic end block polymer or the mid polymer block in case of a triblock copolymer."

[0048] "The amphiphilic block co-polymers are made from two or more blocks of hydrophilic monomers or hydrophobic monomers. The polymers may for instance be a diblock having a structure AB, where A is a hydrophobic block and B is a hydrophilic block or a triblock having a linear structure ABA where A is a hydrophobic block and B is a hydrophilic block, or alternatively have the form of a multi block or three or multi arm star-shaped copolymer structure, containing A and B blocks. Suitably, the amphiphilic block co-polymer is a diblock AB or a triblock ABA, must preferred the amphiphilic block co-polymer is a triblock copolymer ABA."

[0049] "The incorporation of amphiphilic block copolymers having long hydrophobic end blocks into the adhesive composition of the invention improves the cohesion dramatically compared to the incorporation of conventionally used associative thickeners."

Therefore, nowhere applicants had disclosed the hydrophilic polymer as end blocks except in AB block copolymer and it forms mid block in case of ABA block copolymer. Accordingly, applicants were not in possession of the claimed subject matter at the time of the invention.

If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 6-13, 21, 26, 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48858 ('858), IDS filed 07/24/2006, in view of CA 02426251 ('251), IDS filed 11/13/2009, as evident by the article by Wang et al. "Optimum toughening via biocontinuous blending: toughening of PPO with SEBS and SEBS-g-maleic anhydride", currently provided, and further in view of JP 07-070545 ('545), currently provided and GB 1431683 ('683), currently provided.

Applicant Claims

Applicants' currently amended claim 1 is directed to a composition comprising:

- a) one or more hydrogel-forming hydrophilic homopolymers or heteropolymers and
- b) one or more amphiphilic block-copolymers comprising:
 - (i) one or more hydrophobic polymer blocks incompatible with the hydrogel-forming hydrophilic homopolymers or heteropolymers and
 - (ii) one or more hydrophilic polymer end blocks compatible with the hydrogel-forming hydrophilic homopolymers or heteropolymers.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

WO '858 teaches pressure sensitive adhesive composition for application to human or animal skin comprising polyvinyl pyrrolidones polymer (PVP) or PVP copolymer, and block copolymer comprising styrene to improve the rate of absorption of

water and improve integrity and wet tack of the adhesive composition on wet skin (abstract). PVP has capability to absorb water (page 7, lines 13-16), i.e. hydrogel forming polymer. The composition further comprises hydrocolloid selected from polyethylene glycol, which reads on plasticizer claimed by claim 8 (page 9, line 7).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although WO '858 teaches the adhesive composition comprises block copolymer comprising styrene to improve the rate of absorption of water and improve integrity and wet tack of the adhesive composition on wet skin, however, the reference does not explicitly teach amphiphilic block-copolymers comprising hydrophobic polymer blocks and end hydrophilic polymer blocks as instantly claimed by claim 1.

CA '251 teaches amphiphilic block copolymer that is suitable for absorbent agents (abstract). The amphiphilic block copolymer has hydrophilic part and hydrophobic part that has compatibility with hydrophilic compounds and affinity for hydrophilic products therefore enabling the amphiphilic copolymer for the purpose of use as absorption agents. The block copolymer comprises polystyrene blocks and polyethylene glycol blocks (page 2, lines 25-34; page 8, lines 23-28). The hydrophilic polyethylene glycol blocks have molecular weight (MW) from 200-20,000, with MW of 1000-800 is advantageous, average MW 2000 (page 4, lines 22-26; page 5, lines 1-10). The hydrophobic blocks are Kraton G 1091 (page 4, lines 7-10). Kraton G 1901 has an

average molecular weight 7500 in the polystyrene block as evident by Wang et al. (page 38, paragraph 2.1.)

JP '545 teaches adjustable pressure sensitive adhesive suitable for medicine delivery comprising copolymer having hydrophilic part such as polyethylene glycol and hydrophobic part such as styrene polymers (abstract; paragraphs 009-0014). The teaching of the reference implies diblock and triblock copolymers.

GB '683 teaches triblock as well as diblock copolymers comprising styrene polymers and polyethylene polymers, i.e. hydrophilic end block, having low glass temperature (page 1, lines 46-49, 70-90; page 2, lines 85-100; page 4, lines 109-115).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide pressure sensitive adhesive composition for application to human or animal skin comprising polymer or copolymer PVP and block copolymer comprising styrene to improve the rate of absorption of water as taught by WO '858, and replace the block copolymer with amphiphilic block copolymer taught by CA '251, JP '545 and GB '683. One would have been motivated to do so because WO '858 desired to improve water absorption and because CA '251 teaches that amphiphilic block copolymer has hydrophilic part and hydrophobic part that has compatibility with hydrophilic compounds and affinity for hydrophobic products therefore enabled for the purpose of use as absorption agents. Further one would have been motivated to do so

because JP '545 teaches that copolymers, either di- or tri-block, are suitable for medicinal deliver, and because GB '683 teaches both triblock and diblock copolymers are equivalent. One would reasonably expect formulating pressure sensitive adhesive composition for application to human or animal skin comprising polymer or copolymer of PVP and amphiphilic block copolymer that is compatible with hydrophilic product and has affinity to hydrophobic products and has improved absorption properties and medicinal delivery.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

11. Applicant's arguments filed 05/10/2010 have been fully considered but they are not persuasive.

Applicants argue that the PTO relies on the description of an amphiphilic block copolymer in CA '251; in particularly an amphiphilic block copolymer that "comprises polystyrene blocks and polyethylene glycol blocks". The CA '251 is limited to a very specific triblock copolymer, which contain only blocks of styrene polymer and ethylene/butylene polymer, wherein the only "end blocks" of the amphiphilic copolymer are hydrophobic "polystyrene" blocks, with hydrophilic blocks, (i.e., "poly(ethylene/butylene) block containing drafted hydrophilic groups") constituting

midblocks. In other words, the amphiphilic block copolymer disclosed in CA '251 contains no hydrophilic end blocks. WO '858 also does not support the limitation on the present claims to "amphiphilic block copolymers." Accordingly, since "the cited references do not support each limitation of the claims," the §103(a) rejection as applied against the present claims is "inadequate on its face." All limitations on the present claims must be taught or suggested by the cited prior in order to establish prima facie obviousness of the presently claimed invention.

In response to above arguments, it is argued that the present claims are directed to composition, and all the elements of the composition are taught by the combination of the references. CA '251 teaches amphiphilic block copolymer comprising both hydrophobic and hydrophilic blocks and is suitable for absorbent agents, as the present invention. The burden is on applicant to show that the amphiphilic block copolymer having both hydrophobic and end hydrophilic blocks instantly claimed are superior to the amphiphilic block copolymer having both hydrophobic and hydrophilic blocks taught by the prior art. Applicants failed to show unexpected results obtained from having end block hydrophilic polymer rather than mid block. In any event, in view of the new ground of rejection, it shows that it was known at the time of the invention there was no differentiation between di-, and tri-block copolymers in terms of medicinal delivery, and further AB and ABA block copolymers were known as being equivalent in the art and both exhibits the low glass temperature as taught by GB '863.

The combination of the cited references teaches the present invention as a whole. In considering the disclosure of the reference, it is proper to take into account not

only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be

made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject as a whole as matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/

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Primary Examiner, Art Unit 1611